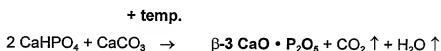


Implementation Examples

1. According to an advantageous embodiment, the ceramic implant material according to the invention can be synthesised from the two inorganic materials calcium hydrogen phosphate and calcium carbonate from stoichiometric mixtures by sintering according to the formula



The synthesis is carried out at temperatures below 1200°C in the β -TCP phase region. In order to avoid the formation of undesirable subsidiary phases such as that of α -TCP, of amorphous phases and of hydroxyapatite, rectification of the material is carried out by sintering several times in the above-mentioned temperature range.

2. Forming of the implant material according to the invention is advantageously carried out by compressing the phase-pure TCP powder to form long cylindrical blanks, baking these at $T < 1200^\circ\text{C}$ and bringing the blanks obtained in that matter into the desired form by means of chip-removing methods (milling, turning and drilling).
3. Manipulable implants can be produced, according to an advantageous embodiment, from the bone replacement material according to the invention, in the form of rod-shaped cylindrical, cuboidal or cube-shaped and other semi-finished products which can be brought into the desired shaped using suitable tools (files, rasps, saws etc.) (cf. **Fig. 2**). Those semi-finished products can be produced by customary compressing techniques from powders but also by pouring techniques of the kind that is customary in ceramics. The tubular porosity according to the invention is produced by drilling and milling after ceramic baking of those shaped articles.
4. Particular implants made from the material according to the invention, which are employed in specific fields of use, can be produced in large numbers in standardised size gradations from blanks by, for example, chip-removing methods. A number of advantageous embodiments are shown in **Fig. 3a-c**. For example, **Fig. 3a** shows a so-called alveolar augmentation article for filling an alveolus after extraction of a tooth;

Fig. 3b shows a conical disc which serves for closure of a trephination opening in the cranium; **Fig. 3c** shows an advantageous embodiment of a flat augmentation article for filling out or raising an atrophied jaw ridge, a so-called sinus lift.

5. 2 mol of calcium hydrogen phosphate and 1 mol of calcium carbonate in powder form were mixed, compressed to make a formed element, transferred to a ceramic crucible and sintered for 24 hours at 1100°C. The sintered element was broken up and ground; 1 % of an unreacted powder mixture of the formulation given above was added thereto and intimately mixed therewith. The mixture was then compressed to make a formed element and again sintered for 24 hours at 1100°C. After cooling, the sintered element obtained was mechanically processed and brought into a form according to Fig. 2e. The formed piece was finally baked again for 24 hours at 950°C.

6. Experimental results

The successful development step for achieving phase-pure β -TCP ceramics is documented by two X-ray recordings (Fig. 4a, 4b). Figure 4a shows the material after the first sinter bake. Still clearly discernible is a residual reflection of hydroxyapatite (arrow). After a first sinter bake, the batch was broken up again, homogenised and compacted again. No unreacted starting material was added to the material. The X-ray powder diffraction diagram still shows a residual reflection of hydroxyapatite after that second sinter bake.

Using a second example, it may be demonstrated that the hydroxyapatite foreign phase is, surprisingly, no longer discernible as a result of the addition of unreacted starting material to a batch of β -TCP baked once. After the first sinter bake, the batch K 286 clearly shows a HA reflection at about $31.7^\circ 2\theta$. After again powdering the pre-synthesised material and mixing with unreacted phosphate powder, the resulting material was also subjected to a second sinter bake. In Figure 5b, an HA reflection is no longer discernible.

It is accordingly possible here to demonstrate impressively that the formation of HA is completely suppressed as a result of dissolution thereof in the melt after unreacted material is added, with, at the same time, seed formation being facilitated by the β -TCP already present.

PCT Chapter II

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Curasan AG

Heide et al.;

resorbable bone replacement and bone formation material

Patent claims

1. Resorbable bone replacement and bone formation material (augmentation material) based on porous β -tricalcium phosphate (β -TCP), which **can be produced by**

(a) baking a phosphate powder of a chemical composition the residue on baking of which yields theoretically chemically pure tricalcium phosphate and

(b) providing the baked blanks with tubular pores,

characterised in that

β -tricalcium phosphate (β -TCP) is baked at least twice and especially at least three times and the formation of the thermodynamically stable adjacent phases of β -TCP is prevented by

- (i) powdering the presynthesis product obtained according to step (a),
- (ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (a) and powdering the material obtained and optionally repeating step (ii) once or more than once,

- (iii) compressing the powdered product obtained in step (i) or step (ii) together with phosphate powder according to step (a) to form blanks and subjecting the blanks formed to final ceramic baking and
 - (iv) subjecting the compressed or baked blanks, at least 99.5 % of which consists of pure β -tricalcium phosphate (β -TCP), to step (b).
2. Formation material according to claim 1, **characterised** in that the chemical and crystalline purity, the fabric structure, the microporosity and the macroporosity of the augmentation material make possible rapid, foreign-body-reaction-free, biochemically orientated integration and resorption in bone.
3. Formation material according to one of the preceding claims, which can be produced by
- (i) starting from a presynthesis product **obtainable** by baking a phosphate powder of a chemical composition the residue on baking of which yields theoretically chemically pure tricalcium phosphate as a presynthesis product, and powdering that presynthesis product,
 - (ii) optionally baking the powdered presynthesis product together with phosphate powder according to step (i) and powdering the material obtained and optionally repeating step (ii) once or more than once,
 - (iii) compressing the powdered product obtained in step (i) or step (ii) together with phosphate powder according to step (i) to form blanks and subjecting the blanks formed to final ceramic baking and
 - (iv) providing the compressed or baked blanks with tubular pores.
4. Formation material according to claim 1 or 3, **obtainable** by baking at a temperature below 1200°C in the β -tricalcium phosphate (β -TCP) phase region.

5. Formation material according to one of claims 1, 3 or 5, **obtainable** by using in step (ii) and/or step (iii) from 1 to 50 % by weight, especially from 1 to 25 % by weight, phosphate powder (based on the total weight of phosphate powder and already baked material).
6. Formation material according to one of the preceding claims, **characterised** in that the sintered structure has a uniform, interconnected microporosity having pore widths in the region of from 2 to 15 μm and especially from 4 to 10 μm and/or the matrix of the augmentation material is tightly sintered to microporosity, especially with microparticles that are loosely bound in the sintered structure and/or phagocytosable, having a diameter of max. 15 μm , being absent.
7. Formation material according to one of the preceding claims, **characterised** by a microporosity of 20 % by volume or more, preferably from 20 to 40 % by volume, and especially 30 % by volume or more, based on the overall porosity (consisting of micro- and macro-porosity).
8. Formation material according to one of the preceding claims, **obtainable** by providing the compressed blank with tubular pores with the aid of a compression mould of optionally more than one part.
9. Formation material according to one of the preceding claims, **obtainable** by providing the baked blank with tubular pores by means of milling or drilling.
10. Formation material according to one of the preceding claims, **characterised** in that the formation material is in block form, with 2- or 3-dimensionally oriented macroscopic tubular pores passing through each block, which are in each case arranged perpendicular to the block surface or to an imaginary plane laid through the block or against the block and form an interconnecting system of tubular pores.
11. Formation material according to claim 10, **characterised** in that a block intended for implantation, together with its tubular pores, can be so oriented for implantation or on processing prior to implantation that at least one direction of orientation of the tubular pores corresponds to a biomechanically or biofunctionally intended direction of growth.

12. Formation material according to one of the preceding claims, **characterised** by tubular pores that have radii in the region of from 100 to 2000 μm and especially from 500 to 2000 μm .
13. Formation material according to one of the preceding claims, **characterised** in that the formation material, present in block form, is penetrated by the tubular pores spaced apart at a defined spacing with respect to one another, especially at a spacing that corresponds to a wall thickness of not more than from 1500 to 4000 μm and especially from 2000 to 3000 μm .
14. Formation material according to one of the preceding claims, **characterised** by an overall porosity (consisting of micro- and macro-porosity) of more than 50 % by volume.
15. Formation material according to one of the preceding claims, **characterised** by a macroporosity of from 25 to 50 % by volume, and especially from 30 to 40 % by volume, based on the overall porosity (consisting of micro- and macro-porosity).
16. Formation material according to one of the preceding claims, **characterised** in that the block form is a simple geometric shape, especially that of a cube, cuboid, taper, cone or disc.
17. Formation material according to one of the preceding claims, **characterised** in that it is a semi-finished product, especially for subsequent mechanical processing, preferably for individual adaptation in the case of a bone defect in mouth or jaw medicine, orthopaedic surgery or trauma surgery.
18. Formation material according to one of claims 11 to 17, **characterised** in that the material is compressed, especially baked or sintered, only to a degree such that it can be processed using tools available to the practitioner, especially using a rasp, file, scalpel or a dentist's instrument.

19. Formation material according to one of claims 11 to 17, **characterised** in that it has been brought into the form of an individual prosthesis with the aid of a medical CAD/CAM method.